

Law's performativities: shaping the emergence of regenerative medicine through European Union legislation

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Abstract

The paper undertakes a textual and documentary analysis of the Advanced Therapy Medicinal Products Regulation, which was passed into law in the European Union (EU) in 2007. This law is significant for the development of regenerative medicine in the EU and globally. Regulatory texts such as this one provide significant material for addressing key concerns in recent theorising about innovative technologies in socio-legal studies, innovation studies, and science and technology studies. These concerns include expectations about future technologies and economic sectorbuilding. By revisiting philosopher J.L. Austin's well-known work on *How to Do Things with Words*, this paper deploys his concepts of performative utterances to inform its analysis. Pursuing Austin's and later commentators' analysis of performatives in language use, and drawing on Lindsay Prior's application of actor-network theory to documents, the analysis shows two different types of performativity at work in and through the document. These are termed 'generative' and 'enactive' performativity. The 'enactive' type includes 'legislative' and 'social' forms. In addition, a more conventional content analysis reveals a range of actions, both legislative and discursive, in the regulatory document. The analysis shows a tension between standardisation and imprecision in the conceptual detailing of the document. Legislative texts produced through established politicolegal conventions are a special class of document that should be accorded a more prominent place in understanding the role of political governance processes in shaping emergent technoscientific fields and sectors.

Keywords

European Union, innovation studies, law, performativity, regenerative medicine, textual/document analysis